

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA; the States of
CALIFORNIA, COLORADO, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA, LOUISIANA,
MASSACHUSETTS, MICHIGAN, MINNESOTA,
MONTANA, NEVADA, NEW JERSEY, NEW
MEXICO, NEW YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND, TENNESSEE,
TEXAS, VIRGINIA, WASHINGTON and
WISCONSIN; the DISTRICT OF COLUMBIA;
THE CITY OF CHICAGO and THE CITY OF
NEW YORK, ex rel., CHARLES ARNSTEIN
and HOSSAM SENOUSY,

Plaintiffs and Relators,

vs.

TEVA PHARMACEUTICALS USA, INC.,
TEVA NEUROSCIENCE, INC., and TEVA
SALES AND MARKETING, INC.,

Defendants.

No. 13 Civ. 3702 (CM)

**SUPPLEMENTAL COUNTERSTATEMENT OF PLAINTIFFS-RELATORS,
CHARLES ARNSTEIN AND HOSSAM SENOUSY, PURSUANT TO
LOCAL CIVIL RULE 56.1(b) AND THE COURT'S ORDER
DATED DECEMBER 11, 2018**

Plaintiffs-Relators, Charles Arnstein and Hossam Senousy ("Relators"), pursuant to Rule 56 of the Federal Rules of Civil Procedure, Local Civil Rule 56.1 and the Court's Order dated December 11, 2018, by their undersigned counsel, hereby submit this Supplemental Counterstatement of Material Facts in Opposition to Defendants' Motion for Summary Judgment

(“Motion”).¹ Pursuant to Local Civil Rule 56.1, Relators respond as follows:

1. Promotional events like Speaker Programs are an inherently risky practice for a pharmaceutical manufacturer because the programs provide remuneration to HCPs. Payments or transfers of value by pharmaceutical manufacturers to HCPs, who are also prospective customers for the manufacturers’ products, may trigger potential violations under the AKS and the FCA. A payment may violate these laws if any one purpose of such a payment is to induce an HCP to prescribe a certain medication or refer a patient for treatment covered by a federal health care program. *See* Pl. Ex. 284 at 5.

2. The AKS addresses the possibility that when a person is in a position to control from where a Medicare patient purchases an insured item or service and is paid for that referral, the referral will not be made with the patient’s best interests in mind and the overall cost of health care will be driven up by the payment of referral fees. *Id.* at f.n. 71, *citing* “Prosecuting and Defending Health Care Fraud Cases,” Michael K. Loucks and Carol C. Law, The Bureau of National Affairs, Inc., Washington D.C. (2003), p. 146-148.

3. At all pertinent times, Teva was aware that its Speaker Programs could result in violations of the AKS. *See* Pl. Ex. 391 at TNA-0244587 (recounting that Teva’s Director of Compliance attended a Speaker Program and stated that, through Teva’s Speaker Programs, it [REDACTED]); Pl. Ex. 197 at ¶ 8 (Teva’s Director of Compliance stating that “[throughout [his] career at Teva, [he] consistently was concerned that its [S]peaker [P]rograms could raise kickback perceptions”); Pl. Ex. 344

¹Plaintiffs adopt the same definitions as contained in their Rule 56.1 Statement dated September 13, 2018 for the convenience of the Court.

(testimony of Amy Deakin at 289:20-293:12 regarding concerns by Teva's Director of Compliance that Teva's Speaker Programs [REDACTED]); Pl. Ex. 198 at TNA-0237743 (in which Teva acknowledges that payments to Speakers could result in "[REDACTED]"); Pl. Ex. 303 at TNA-0462845 (in which Teva's consultant states that "[REDACTED]"); Pl. Ex. 227 at TNA-0213414 (2010 Teva Speaker Agreement for Promotional Programs acknowledging that Speakers [REDACTED]); Def. Ex. 50 at TNA-0625526 (sample Teva Speaker Agreement for Promotional Programs acknowledging that Speakers [REDACTED]); Def. Ex. 51 at TNA-0190256 (2011 Teva Speaker Agreement for Promotional Programs acknowledging that Speakers [REDACTED]); Def. Ex. 52 at TNA-0244572 (2012 Teva Speaker Agreement for Promotional Programs acknowledging that Speakers [REDACTED]).

4. Teva also was aware that, if it paid an HCP or provided anything of value to an HCP with the expectation that a prescription for the covered drugs would be written in return, such activities would violate the AKS. *See also* Def. Ex. 124 at 128:14-129:8 (in which Michael Mercer, a Teva Regional Sales Manager, acknowledges that [REDACTED] [REDACTED] [REDACTED]).

5. Teva failed to adopt an effective compliance program to avoid violations of the

AKS with respect to its Speaker Programs despite its knowledge that the Speaker Programs could result in AKS violations. Pl. Ex. 284 at 5-46; Pl. Ex. 197 at ¶ 10 (Teva's monitoring of its Speaker Programs was "limited and infrequent in nature" according to Teva's Director of Compliance); Pl. Ex. 197 at ¶ 12 (Teva's Director of Compliance faced push-back from Teva's senior management when he attempted to improve compliance procedures with respect to Speaker Programs).

6. Teva took steps to conceal problems in its Speaker Programs by mandating that issues with its Speaker Programs [REDACTED] " [REDACTED]" Def. Ex. 118 at TNA-0178955, and by actively concealing the poor attendance at its Speaker Programs by including Teva Speakers and Teva employees in the number of attendees. *See, e.g.*, Pl. Ex. 271.

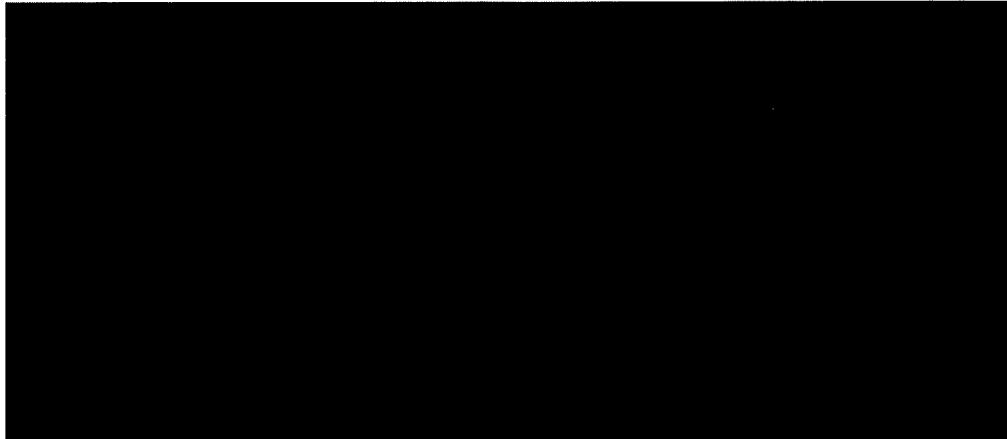
7. At all pertinent times, compliance with the AKS has been a condition of participation and payment for the Government Healthcare Programs. *See* Pl. Ex. 284 at 46-48.

8. At all pertinent times, Teva knew and treated the AKS as a significant and important law that applied to the Speaker Programs, and knew that the United States would refuse to pay claims based on noncompliance with the AKS and could seek penalties, recoupment of payments and could exclude pharmaceutical manufacturers, such as Teva, from participating in Government Healthcare Programs, based upon its violations of the AKS:

a. In 2007, Teva acknowledged in its Teva Integrity Principles ("TIPS") as follows:

[REDACTED]





Def. Ex. 12 at TNA-0722060 (emphasis added).

b. In its 2008 TIPS, Teva also acknowledged that the federal government treated payments for products and services attributable to AKS violations as [REDACTED]

[REDACTED] and that [REDACTED]

[REDACTED]

[REDACTED] Def. Ex.

112 at TNA-0625461-TNA-0625462 (emphasis added).

c. In its 2009 TIPS, Teva again acknowledged that the federal Government treated payments for products and services attributable to AKS violations as [REDACTED]

[REDACTED]

Def. Ex. 13 at TNA-0596783-TNA-0596784 (emphasis added); *see also* Def. Ex. 126 at TNA-0001637-TNA-0001638 (same).

d. Teva instituted [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Def. Ex. 123 at TNA-0538324, which CIA (https://oig.hhs.gov/fraud/cia/agreements/ivax_corporation_10302009.pdf) required the development of policies, procedures, and training regarding the AKS, as well as compliance with the AKS and actions taken to identify, quantify and repay any overpayments to Federal Healthcare Programs, creating an arrangements database and assigning individuals to track arrangements that implicate potential AKS concerns. CIA at 5-7, 8-10, 21-22, Appendices A and B.


e. In Teva's 2010 Corporate Compliance Presentation for New Hires (Def. Ex. 121 at 5-6, 9-10), Teva acknowledged that the [REDACTED]

[REDACTED]

f. In a Teva Corporate Compliance presentation dated July 28, 2010 (Def. Ex. 108 at 23-24, 27-28), Teva acknowledged the importance of the [REDACTED]


[REDACTED]

g. In a 2010 Teva Compliance Update addressing the "Harmonization of Fair Market Value Compensation and Promotional Programs," Teva acknowledged the requirements of the [REDACTED]



Def. Ex. 40 at 1, 3-4, 7.

h. Teva's same 2010 Compliance Update addressing the "Harmonization of Fair Market Value Compensation and Promotional Programs," acknowledged the fact that



Def. Ex. 40 at 12.

i. As early as May 5, 2003, the U.S. Department of Health and Human Services, Office of Inspector General ("HHS OIG"), in its OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) ("2003 OIG Guidance"), recognized that relationships with HCPs, such as arranging for Speaker Programs, could result in AKS concerns and that the 2002 PhRMA Code provided useful and practical advice for structuring relationships with HCPs to reduce the risk of fraud and abuse and demonstrate a good-faith effort to comply with the AKS. Def. Ex. 105 at 11-12.

j. From 2006 to 2008, a number of pharmaceutical companies were placed under CIA obligations with respect to Speaker Programs and were required to establish policies and procedures designed to ensure that these Speaker Programs were “legitimate and lawful in accordance with Federal health care program and FDA requirements.” Def. Ex. 105 at 14, *citing* Cephalon CIA (discussed below), available at <http://www.pharmacomplianceforum.org/docs/resources/CephalonCIA.pdf> (also available at <https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf>), and www.pharmacomplianceforum.org/docs/resources/php (providing links to over 30 CIAs from 2005 to 2009 (also available at <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>)).

k. A CIA entered into between the HHS OIG and Cephalon, Inc. (a company subsequently acquired by Teva in 2011), on September 29, 2008 (“Cephalon CIA”), specifically addressed Speaker Programs and required compliance with the AKS. Def. Ex. 105 at 13-14, 48, *citing* Cephalon CIA, available at <http://www.pharmacomplianceforum.org/docs/resources/CephalonCIA.pdf> (also available at <https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf>).

l. On January 1, 2009, a revised 2009 PHRMA Code was adopted and included a new section on Speaker Programs, including the expectation that companies would develop policies to address caps on engagements and compensation for Speakers. Def. Ex. 105 at 15-16.

m. On January 14, 2009, OIG and Eli Lilly & Co. entered into a CIA (the “Eli Lilly CIA”), addressing Speaker Programs and requiring compliance with the AKS. Def. Ex. 105 at 16, *citing* <http://www.pharmacomplianceforum.org/html/resources.php> (also available at

<https://assets.documentcloud.org/documents/10662/eli-lilly-and-company-01142009.pdf>).

n. On August 31, 2009, HHS, OIG and Pfizer, Inc. entered into a CIA (the “Pfizer CIA”), which imposed significant requirements regarding Speaker Programs, including tracking attendees and expenditures on Speakers, and required compliance with the AKS. Def. Ex. 105 at 16-17, *citing* <http://www.pharmacomplianceforum.org/html/resources.php> (also available at https://oig.hhs.gov/fraud/cia/agreements/pfizer_inc.pdf).

o. On September 11, 2009, OIG and Biovail Corp. entered into a CIA (the “Biovail CIA”), addressing Speaker Programs and required compliance with the AKS. Def. Ex. 105 at 16, *citing* <http://www.pharmacomplianceforum.org/html/resources.php> (also available at <https://contracts.onecle.com/valeant/dhhs-integrity-2009-09-11.shtml>).

p. Between August 2009 and December 31, 2014, a significant number of CIAs were entered into between OIG and pharmaceutical manufacturers and these CIAs included similar provisions regarding Speaker Programs and the AKS to those included in the Pfizer CIA. Def. Ex. 105 at 17.

q. In April, 2010, Ortho-McNeil Pharmaceutical LLC and Ortho-McNeil-Janssen Pharmaceuticals, Inc. entered into a CIA in which Speakers were defined as consultants and subject to annual needs assessments and a business rationale process with specific references to requirements for compliance with the AKS. Def. Ex. 105 at 17-18, *citing* U.S. Attorney’s Office, District of Massachusetts Press Release, *Ortho-McNeil Pharmaceuticals, LLC Pleads Guilty to Illegal Promotion of Topamax and is Sentenced to Criminal Fine of \$6.14 million*, <https://www.justice.gov/archive/usao/ma/news/2010/OrthoMcNeilSentencingPR.html> (addressing payments to doctors)(also available at <https://archives.fbi.gov/archives/boston/>

[press-releases/2010/bs052110.htm](http://www.pharmacomplianceforum.org/html/press-releases/2010/bs052110.htm)); <http://www.pharmacomplianceforum.org/html/resources.php> (also available at <https://policymed.typepad.com/files/orhtomcneil-cia-4-29-10.pdf>).

r. In May, 2011, the DOJ entered into a settlement with EMD Serono addressing allegations with respect to improper payments related to speaker programs, speaker training meetings, advisory boards and consultant meetings, and required compliance with the AKS. Def. Ex. 105 at 18, *citing* <http://www.pharmacomplianceforum.org/html/resources.php>.

s. There were additional CIAs entered into between OIG and pharmaceutical companies addressing Speaker Programs in 2010, 2011 and 2012. Def. Ex. 105 at 18, n. 87, *citing* a CIA with Novartis Pharmaceuticals Corporation dated September 29, 2010 (available at https://oig.hhs.gov/fraud/cia/agreements/Novartis_Pharmaceuticals_Corporation_09292010.pdf); a CIA with Novo Nordisk Inc. dated May 31, 2011 (available at <https://www.casd.uscourts.gov/Fallbrook/files/13md2452/doc1/3509.pdf>); and a CIA with Boehringer Ingelheim Pharmaceuticals, Inc. dated October 22, 2012 (available at <https://www.corporatecrimereporter.com/wp-content/uploads/2012/10/cia.pdf>), all of which required compliance with the AKS.

t. In December, 2012, OIG entered into a CIA with Amgen Inc. dated December 12, 2012, requiring that compliance controls confirm that there is “a legitimate need for the speaker program,” as well as compliance with the AKS. Def. Ex. 105 at 18 (available at https://oig.hhs.gov/fraud/cia/agreements/Amgen_12142012.pdf).

u. A CIA entered into between OIG and Johnson and Johnson dated October 31, 2013 (available at https://oig.hhs.gov/fraud/cia/agreements/Johnson_Johnson_10312013.pdf),

and a CIA entered into between OIG and Endo Pharmaceuticals, Inc. dated February 14, 2014 (available at https://oig.hhs.gov/fraud/cia/agreements/Endo_Pharmaceuticals_02212014.pdf), likewise included requirements that there be a legitimate need for Speaker Programs and compliance with the AKS. Def. Ex. 105 at 19, n. 90.

v. In the Draft Recommendation for Fair Market Compensation Rates for Healthcare Professionals dated August 28, 2008, Teva's consultant, Huron Consulting Group, advised Teva as follows:



[REDACTED]

Def. Ex. 37 at TNA-0001462 (Appendix A at 135)(emphasis added). [REDACTED]

[REDACTED] *Id.* at TNA-0001464(Appendix A at 137).

In addition, [REDACTED]

[REDACTED]

[REDACTED] *Id.* at TNA-

0001467 (Appendix A at 140). [REDACTED]

[REDACTED]

[REDACTED] *Id.* Moreover, [REDACTED]

[REDACTED]

[REDACTED] *Id.* at TNA-0001469 (Appendix A at 142).

w. In an updated “Recommendation of Fair Market Compensation Rates for Healthcare Professionals,” with valuations being provided as of July 24, 2008 and amendments as of August 16, 2010, [REDACTED]

[REDACTED]

[REDACTED] *See* Def. Ex. 38 at TNA-0001304 to TNA0001312

(Appendix A2 at 169-177).

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SHEPHERD FINKELMAN MILLER
& SHAH, LLP

/s/ Laurie Rubinow
James E. Miller
Laurie Rubinow
65 Main Street
Chester, CT 06412
Telephone: (860) 526-1100
Facsimile: (866) 300-7367
Email: jmiller@sfmslaw.com
lrubinow@sfmslaw.com

James C. Shah
SHEPHERD, FINKELMAN, MILLER
& SHAH, LLP
Natalie Finkelman Bennett
Bruce D. Parke
35 E. State Street
Media, PA 19063
Telephone: (610) 891-9880
Facsimile: (866) 300-7367
Email: jshah@sfmslaw.com
nfinkelman@sfmslaw.com
bparke@sfmslaw.com

Nathan C. Zipperian
SHEPHERD, FINKELMAN, MILLER
& SHAH, LLP
1625 North Commerce Parkway, Suite 320
Fort Lauderdale, FL 33326
Telephone: (954) 515-0123
Facsimile: (866) 300-7367
Email: nzipperian@sfmslaw.com

Chiharu G. Sekino
Kolin Tang
SHEPHERD, FINKELMAN, MILLER
& SHAH, LLP
401 West 'A' Street, Suite 2550
San Diego, CA 92101
Tel: (619) 235-2416
Fax: (866) 300-7367
Email: csekino@sfmslaw.com
ktang@sfmslaw.com

Eric L. Young
James J. McEldrew, III
Brandon J. Lauria
McELDREW YOUNG
123 S. Broad Street, Suite 2250
Philadelphia, PA 19109
Telephone: (215) 367-5151
Facsimile: (215) 367-5143
Email: eyoung@mceldrewyoung.com
jmceldrew@mceldrewyoung.com
blauria@mceldrewyoung.com

David J. Caputo
YOUMAN & CAPUTO
1650 Market Street, 36th Floor
Philadelphia, PA 19103
Telephone: (215) 302-1999
Facsimile: (610) 808-1772
Email: dcaputo@youmancaputo.com

David A. Bocian
KESSLER TOPAZ MELTZER & CHECK, LLP
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
Facsimile: (610) 667-7056
Email: dbocian@ktmc.com

Attorneys for Plaintiffs-Relators